

- 1 1. (Original) A water dispersible tablet formulation comprising an active ingredient as
2 beta lactam antibiotic and optionally a beta lactamase inhibitor, a disintegrating agent,
3 said disintegrating agent being used both intragranularly and extragranularly, and
4 pharmaceutically accepted excipients.
- 1 2. (Original) The formulation of claim 1 wherein said β -lactam antibiotic is selected
2 from the group consisting of penicillin, cephalosporin and carbapenam.
- 1 3. (Original) The formulation of claim 1 wherein said penicillin is amoxicillin, said
2 cephalosporins is cefuroxime axetil, cefpodoxime proxetil or cefalexin and said
3 carbapenam is loracarbef or imipenem.
- 1 4. (Original) The formulation of claim 1 comprising the disintegrant selected from the
2 group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.
- 1 5. (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about
2 2.5 % w/w of an ~~the~~ intragranular disintegrant.
- 1 6. (Currently Amended) The formulation of claim 1 ~~or 4~~ comprising about 1 % to about
2 5 % w/w of an ~~the~~ extragranular disintegrant.
- 1 7. (Currently Amended) The formulation of claim 1 comprising a ~~the~~ filler selected from
2 the group consisting of lactose, microcrystalline cellulose and starch.
- 1 8. (Currently Amended) The formulation of claim 1 further ~~or 7~~ comprising 40-70 %
2 w/w of a ~~said~~ filler.
- 1 9. (Original) The formulation of claim 1 comprising the lubricants selected from the
2 group consisting of talc, magnesium stearate, stearic acid and colloidal silicon
3 dioxide.

- 1 10. (Original) The formulation of claim 1 wherein said dispersible tablet has a
2 disintegration time of less than one minute.
- 1 11. (Currently Amended) The formulation of claim 1 wherein said tablets form
2 suspension after incorporating in aqueous media~~water~~.
- 1 12. (Original) The formulation of claim 11 wherein said suspension formed completely
2 passes through a 750 μ m sieve.
- 1 13. (Original) The formulation of claim 1 wherein said beta lactamase inhibitor is
2 clavulanic acid or a salt thereof.
- 1 14. (Original) The formulation of claim 13 wherein the clavulanic acid salt is potassium
2 clavulanate.
- 1 15. (Currently Amended) The formulation of claim ~~13 or~~ 14 wherein the ratio of
2 amoxicillin to potassium clavulanate is 12:1 to 1:1.
- 1 16. (Original) The formulation of claim 15 wherein the ratio of amoxicillin to potassium
2 clavulanate is 7:1.
- 1 17. (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d90 less than 600
3 μ m.
- 1 18. (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d90 less than 400
3 μ m.
- 1 19. (Currently Amended) The formulation of claim ~~1 or~~ 11 wherein the tablet when
2 dispersed in an aqueous media, has a particle size distribution of d50 less than 300
3 μ m.

- 1 20. (Currently Amended) A process for the preparation of a dispersible tablet comprising
2 a beta lactam antibiotic, an optional beta lactamase inhibitor and an intragranular
3 disintegrant, ~~said the process comprising: aqueous granulating of a beta lactam~~
4 antibiotic, an optional beta lactamase inhibitor and an said intragranular disintegrant
5 incorporated either in the dry mix or the granulating fluid, ~~are aqueous granulated,~~
6 ~~dried, mixed; drying the granulation; missing the dried granulation with the~~
7 extragranular disintegrant, a filler, a flavour, a lubricating agent, and a sweetener; and
8 compressing the resulting blend ~~is compressed to into~~ tablets.
- 1 21. (Currently Amended) The process of claim 20 wherein the tablet
2 ~~comprising~~comprises 30-50 % w/w amoxicillin.
- 1 22. (Currently Amended) The process of claim ~~20 or~~ 21 wherein the amoxicillin has a
2 particle size of d_{90} less than 150 μm .
- 1 23. (Currently Amended) The process of claim ~~20 or~~ 21 wherein the amoxicillin has a
2 particle size of d_{90} less than 75 μm .
- 1 24. (Currently Amended) The process of claim ~~20 or~~ 24 wherein the tablet comprising
2 comprises about 1 % to about 2.5 % w/w of intragranular disintegrant.
- 1 25. (Currently Amended) The process of claim ~~20 or~~ 24 wherein the tablet comprising
2 comprises about 1 % to about 5 % w/w of extragranular disintegrant.
- 1 26. (Original) The process of claim ~~24 or~~ 25 wherein the disintegrant is selected from the
2 group consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.
- 1 27. (New) The process of claim 25 wherein the disintegrant is selected from the group
2 consisting of croscarmellose sodium, polyvinylpyrrolidone and sodium starch
3 glycolate.

- 4 28. Cancelled.
- 1 29. Cancelled.
- 1 30. Cancelled.
- 1 31. (Original) The process of claim 20 wherein said granules are dried to an equilibrium
2 relative humidity of less than at 40% at a bed temperature of not more than 60°C.
- 1 32. (Currently Amended) The process of claim ~~20~~28 wherein said granules are dried to an
2 equilibrium relative humidity of less than 25% at a bed temperature of not more than
3 50°C.
- 1 33. (Original) The process of claim 20 wherein said dispersible tablet has a disintegration
2 time of less than one minute.
- 1 34. (Currently Amended) The process of claim 20 wherein the comprising beta lactamase
2 inhibitor is as clavulanic acid or a salt thereof, and the beta lactam antibiotic is as
3 amoxicillin.
- 1 35. (Currently Amended) The process of claim ~~33~~31 wherein the clavulanic acid salt is
2 potassium clavulanate.
- 1 36. (Currently Amended) The process of claim ~~33 or 34~~32 wherein the ratio of
2 amoxicillin to potassium clavulanate is 12:1 to 1:1.
- 1 37. (Currently Amended) The process of claim ~~35~~33 wherein the ratio of amoxicillin to
2 potassium clavulanate is 7:1.
- 1 38. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d90 less than 600 µm.
- 1 39. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d90 less than 400 µm.

- 1 40. (Original) The process of claim 20 wherein the tablet when dispersed in an aqueous
2 media, has a particle size distribution of d50 less than 300 μm .
- 1 41. (Currently Amended) A process for the preparation of a water-dispersible tablet
2 formulation, the process comprising:
- 3 aqueous granulation of a β -lactam antibiotic and an intragranular disintegrant,
4 incorporated either in the dry mix or in the granulating fluid;
- 5 drying the granulated mixture;
- 6 mixing the dried granules with optional extragranular disintegrants, fillers,
7 flavours, sweeteners, or lubricating agents; and ~~comprising~~ compressing the
8 resulting blend to form water-dispersible tablets.
- 1 42. (Currently Amended) The process of claim ~~40~~38, wherein the β -lactam antibiotic is
2 selected from penicillins; cephalosporins; and carbapenems.
- 1 43. (Currently Amended) The process of claim ~~40~~38, wherein the β -lactam antibiotic is
2 amoxicillin.
- 1 44. (Currently Amended) The process of claim ~~40~~38, wherein the disintegrant is selected
2 from croscarmellose sodium, polyvinylpyrrolidone, and sodium starch glycolate.
- 1 45. (Currently Amended) The process of claim ~~43~~41, wherein the intragranular
2 disintegrant is croscarmellose sodium.
- 1 46. (Currently Amended) The process of claim ~~43~~41, wherein the disintegrant is present
2 intragranularly at a concentration of about 1 % to about 2.5 % w/w of the tablet
3 formulation.
- 1 47. Cancelled.
- 1 48. Cancelled.

- 1 49. Cancelled.
- 1 50. Cancelled.
- 1 51. Cancelled.
- 1 52. Cancelled.
- 1 53. (Currently Amended) The process of claim 4038, wherein the suspension formed
2 upon dispersion can completely pass through a 750 μm sieve.
- 1 54. A process for the preparation of a stable amoxicillin dispersible tablet formulation,
2 ~~wherein amoxicillin and intragranular disintegrant, incorporated either in the dry mix~~
3 ~~or in the granulating fluid the process comprising: granulation of amoxicillin and~~
4 intragranular disintegrant; drying the granulated mixture; mixing the dried granules
5 with optional extragranular disintegrants, fillers, flavours, sweeteners, or lubricating
6 agents; and ~~comprising~~compressing the resulting blend to form water-dispersible
7 tablets, wherein amoxicillin and intragranular disintegrant are incorporated either in
8 the dry mix or in the granulating fluid.
- 1 55. (Currently Amended) The process of claim 5345, wherein amoxicillin comprises
2 about 30 to about 50 % w/w of the formulation.
- 1 56. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle
2 size of d_{90} less than about 150 μm .
- 1 57. (Currently Amended) The process of claim 5345, wherein amoxicillin has a particle
2 size of d_{90} less than about 75 μm .
- 1 58. Cancelled.
- 1 59. Cancelled.
- 1 60. Cancelled.

- 1 61. Cancelled.
- 1 62. Cancelled.
- 1 63. Cancelled.
- 1 64. Cancelled.
- 1 65. Cancelled.
- 1 66. (Currently Amended) The process of claim ~~53~~45, wherein the granules are dried to an
2 equilibrium relative humidity of less than about 40% at a bed temperature of not more
3 than about 60°C.
- 1 67. (Currently Amended) The process of claim ~~65~~45, wherein the granules are preferably
2 dried to an equilibrium relative humidity of less than about 25% at a bed temperature
3 of not more than about 50°C.
- 1 68. Cancelled.
- 1 69. Cancelled.
- 1 70. Cancelled.
- 1 71. Cancelled.
- 1 72. Cancelled.
- 1 73. Cancelled.
- 1 74. (Currently Amended) ~~The A-process of claim 45 for the preparation of a water-~~
2 ~~dispersible tablet formulation~~ wherein the tablet when dispersed in an aqueous media,
3 has a particle size distribution of d90 less than 600 µm.

